UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, and WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS and VIRGINIA; and THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, Plaintiffs, v. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, and JOHNSON & JOHNSON Defendants.	Civ. No. 19-12107 (KM) (ESK) Document electronically filed Motion return date: May 15, 2023

NONPARTY MYLAN PHARMACEUTICALS INC.'S BRIEF IN SUPPORT OF MOTION TO QUASH NONPARTY SUBPOENA

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Third Party Mylan Pharmaceuticals Inc. ("MPI"), by and through its undersigned counsel, respectfully requests, pursuant to Federal Rules of Civil Procedure 26 and 45, that the Court quash Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson's (together "Janssen") subpoena requesting the production of MPI's confidential documents related to its generic abiraterone acetate products.

I. INTRODUCTION

MPI is not a party to the present *qui tam* litigation, in which Plaintiff-Relator Zachary Silbersher ("Silbersher" or "Relator") alleges Janssen unlawfully delayed generic competition for its Zytiga®-branded abiraterone drug product beyond the December 2016 expiration of Janssen's U.S. Patent No. 5,604,213 ("'213 patent"), which claimed the abiraterone drug substance in Zytiga®.[1] According to Relator, Janssen knew "at least fourteen generic manufacturers were ready, willing, and able to introduce generic competition to Zytiga when the '213 Patent expired." ECF No. 1 ¶ 4.

Janssen's third-party subpoena improperly seeks broad and burdensome discovery that is not relevant to any issue in the proceeding. The requested documents include, *inter alia*, highly confidential and sensitive regulatory, business, and commercial documents dating back more than a decade. These requests purportedly relate to Relator's underlying *qui tam* theory, which this Court has already called "borderline speculative." *United States ex rel. Silbersher v. Janssen Biotech, Inc.*, 2022 WL 17250563, at *4 (D.N.J. Nov 28, 2022) (denying Relator's motion to compel discovery of MPI's documents from the underlying ANDA case).

[1] Janssen also owned U.S. Patent No. 8,822,438 ("'438 patent"), which claimed a method of treating prostate cancer using abiraterone acetate and prednisone. Janssen asserted the '438 patent against MPI before the '213 patent expired.

At least as related to MPI, the theories in this *qui tam* litigation and the related burdensome discovery sought by both Janssen and the Relator[2] suffer from at least three fundamental flaws:

(1) MPI, along with many other ANDA filers, filed its ANDA at the very first opportunity allowed by law, the so-called NCE-1 date. Ex. A (Approval letter for MPI's ANDA No. 208446) at 1 (showing ANDA received for review on April 28, 2015). This date is set by federal law and was based, in this instance, on the original approval date of Janssen's branded abiraterone product, Zytiga. *No* party could have filed an abiraterone ANDA any earlier. The FDA is subject to strict rules promulgated under the Generic Drug User Fee Amendments ("GDUFA")[3] addressing the time to approve or not approve any ANDA and to issue any deficiency letters to the ANDA filer. At all relevant times here, the FDA was acting under the GDUFA II commitment letter,[4] which provided the timelines under which the FDA was to address MPI's ANDA. In short, the FDA was obligated to approve MPI's ANDA as soon as the ANDA was approvable under the FDA's review standards, with two types of approval possible. First, if the ANDA was approvable under the FDA's standards while patent or regulatory exclusivities prevented the marketing of MPI's product, the FDA would have issued only a *tentative* approval of the ANDA. Indeed, that occurred with respect to at least two ANDA filers, Amneal Pharmaceuticals and Wockhardt USA, each of which received tentative approval for its ANDA in October 2017, more than a year before MPI received its own approval. Ex. B (Approval letter for Amneal's ANDA No. 208327) at 1, 5

[2] The *qui tam* Relator provided a draft subpoena to "Mylan, Inc.," but the subpoena has not yet been served.

[3] The FDA's website provides an overview of GDUFA. *See* https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments#:~:text=Congress%20enacted%20GDUFA%20to%20ensure,review%20of%20generic%20drug%20applications.

[4] GDUFA II refers to the document "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022." *See* https://www.fda.gov/media/101052/download.

(deeming ANDA product to be "safe and effective for use as recommended in the submitted labeling," but granting only tentative approval on October 27, 2017, because of a blocking exclusivity); Ex. C (Approval letter for Wockhardt's ANDA No. 208380) at 1, 5 (deeming ANDA product to be "safe and effective for use as recommended in the submitted labeling," but granting only tentative approval on October 18, 2017, because of a blocking exclusivity). This demonstrably proves that with respect to the abiraterone ANDAs, the FDA was not dragging its feet in granting approval to approvable ANDAs because of the '438 patent. Second, if the ANDA was approvable while *no* patent or regulatory exclusivities barred the marketing of MPI's product, the FDA would grant *final* approval of the ANDA. That is exactly what happened here with respect to MPI's ANDA—the FDA granted final approval of the ANDA on October 31, 2018, because there were no active patent or regulatory exclusivities and MPI launched shortly afterward. It is an immutable fact that MPI launched as soon as possible after it had the FDA's approval.

(2) With respect to the financial discovery sought by Janssen, the alleged harm here is solely to the Federal government through the Federal government's pharmaceutical acquisition programs. Indeed, the Federal government is considered the true plaintiff in a *qui tam* litigation, with the Relator merely prosecuting the case on the Government's behalf in the hope of securing a financial reward. Neither party has sought discovery from the Federal government yet, which is where the proof of any harm the Federal government suffered resides.

(3) MPI launched its product at the earliest possible opportunity and MPI launched into a competitive market already crowded with multiple other companies and multiple abiraterone products. Whoever the Federal government chose to purchase its products from, and whatever price they paid at that point, was determined by the dynamics of an already-established competitive market that featured both brand and generic products before MPI entered. As the other ANDA

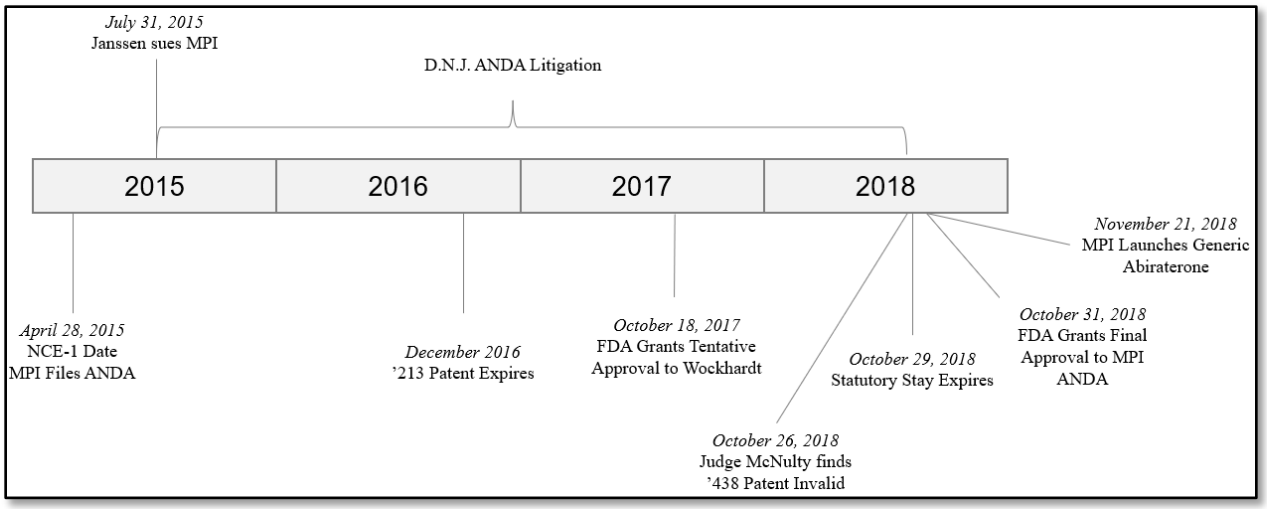
filers note in their motion to quash (ECF No.249), it is both illogical and speculative to believe that companies like MPI undertake the complex and expensive launch planning process years before they can, in fact, launch. They do not. Seeking discovery on issues concerning MPI's ability to launch, based on pure speculation that MPI could do so in advance of the statutory stay in this case is a fishing expedition undertaken in a barren sea.

The Court should quash the subpoena under Rule 45, which requires limiting the burden and expense on non-parties from improper discovery, because the subpoena is procedurally invalid, overbroad, and poses an undue burden. Indeed, another court in this District granted a motion to quash a subpoena that, as here, requested "discovery of documents related to [a generic's] ability to bring [its generic product] to market" and "discovery of [the generic's] sales data of its [generic product]." *SAJ Distribs., Inc. v. Sandoz, Inc.*, 2008 WL 2668953, at *2 (D.N.J. June 26, 2008). Respectfully, this Court should do the same. MPI should not be forced to endure the cost and burden of speculatory theories and discovery.

II. BACKGROUND

A. MPI Filed Its ANDA On the Earliest Possible Date

MPI, along with many other ANDA filers, filed the ANDA for it proposed abiraterone acetate product at the very first opportunity allowed by law, the so-called NCE-1 date. This date (April 28, 2015) was based on the original approval date of Janssen's branded abiraterone product, Zytiga. The FDA approved MPI's ANDA on October 31, 2018, after the expiration of the '213 patent, which claimed the abiraterone compound itself, and the '438 patent, which claimed a method of using abiraterone to treat prostate cancer. Ex. A.



In reviewing MPI's ANDA, the FDA was subject to the rules of GDUFA. Under this Act, the FDA has committed itself to act to approve or not approve any ANDA and to issue any deficiency letters to the ANDA filer by certain statutory deadlines. At all relevant times here, the FDA was acting under the GDUFA II commitment letter, which provided timelines for the FDA to review and approve the substance of MPI's ANDA. By statute, the FDA was obligated to approve MPI's ANDA as soon as the ANDA was approvable, but no sooner. If the ANDA was approvable while patent or regulatory exclusivities prevented marketing of MPI's proposed ANDA product, the FDA would have issued a *tentative* approval. If, on the other hand, *no* patent or regulatory exclusivities prevented marketing of MPI's proposed ANDA product, the FDA would have granted *final* approval. Here, the FDA granted final approval to MPI's ANDA on October 31, 2018, shortly after which MPI launched its generic abiraterone acetate drug product.

B. Other ANDAs and NDAs

Thirteen companies filed ANDAs on the NCE-1 date. *See* Ex. D (FDA Paragraph IV Patent Certifications list) at 1 (entry for abiraterone acetate 250 mg strength, showing 13 ANDAs submitted on April 28, 2015). Like MPI, at least three other ANDA filers received final the FDA's approval on October 31, 2018. Ex. E (Approval letter for Apotex's ANDA No. 208453) at 1, 5

(granting final approval on October 31, 2018); Ex. F (Approval letter for Hikma's ANDA No. 208339) at 1, 5 (granting final approval on October 31, 2018); Ex. G (Approval letter for Teva's ANDA No. 208432) at 1, 5 (granting final approval on October 31, 2018). Other ANDA filers that filed on April 28, 2015, did not receive approval—if they received approval at all—until well after October 31, 2018. Of most import to the issues here, Wockhardt, another company that filed an ANDA on April 28, 2015, received the FDA's approval on October 18, 2017, more than a year before MPI and many of the other ANDA filers. In addition, Sun Pharmaceuticals filed a New Drug Application ("NDA") for its own branded abiraterone acetate product on May 19, 2017, and that application was approved, and Sun launched, on May 22, 2018. Ex. H (Approval letter for Sun's NDA No. 210308) at 1, 4 (granting final approval on May 22, 2018). Thus, contrary to any speculative theory that may be percolating in the qui tam litigation, the FDA's early approval of Wockhardt's ANDA, and its approval in barely more than one year of Sun's NDA, demonstrates the FDA was promptly reviewing and approving any abiraterone acetate drug application when it was approvable, including following its GDUFA obligations to timely act on ANDAs and to approve those generic products as soon as they were approvable.

C. Other Proceedings

1. District Court Litigation

Previously, Janssen and MPI were parties to a patent litigation under the Hatch-Waxman Act (the "ANDA case"). In that case, Janssen asserted that MPI's ANDA No. 208446, which described MPI's proposed abiraterone acetate drug product, infringed another of Janssen's Zytiga®-related patents, U.S. Patent No. 8,822,438 ("'438 patent"), which claimed a method of using abiraterone to treat prostate cancer.

On April 28, 2015, MPI filed an ANDA for its abiraterone acetate tablets. *See* Ex. A

(Approval letter for MPI's ANDA No. 208446) at 1.[5] At the time, both U.S. Patent No. 5,604,213 ("'213 patent") and U.S. Patent No. 8,822,438 ("'438 patent") were listed in the Orange Book for Zytiga. *See* No. 15-cv-5909, ECF No. 1 ¶¶ 58-59; 21 U.S.C. § 355(b)(1). At the same time, the Orange Book listed "NCE" (new chemical entity) exclusivity for Zytiga, expiring on April 28, 2016. Ex. I (excerpts from the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") (35th ed. 2015)) at 5 (listing "NCE Apr 28, 2016"). Based on this NCE exclusivity, the earliest possible filing date for MPI's ANDA related to Zytiga was one year earlier, a date called "NCE-1" (NCE date minus one year), which was April 28, 2015. MPI filed its ANDA on that date. Ex. A.

Janssen filed suit against MPI on July 31, 2015. No. 15-cv-5909, ECF No. 1 ¶ 98. Janssen's filing of a suit triggered an automatic stay of approval of MPI's ANDA, measured from the date that Janssen's ANDA was approved. Thus, absent certain circumstances that did not arise in this case, final approval of MPI's ANDA was prohibited until on or after October 29, 2018.

The litigation that followed the filing of Janssen's complaint ended in the district court issuing an opinion on October 26, 2018, finding the '438 patent invalid as obvious. No. 15-cv-5909, ECF No. 560. The court issued an amended opinion of invalidity of the '438 patent, and entered its final judgment of invalidity, on October 31, 2018. No. 15-cv-5909, ECF Nos. 571, 572; *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 352 F. Supp. 3d 352, 383-89 (D.N.J. 2018).

The FDA approved MPI's ANDA No. 208446 on October 31, 2018. Ex. A.

On October 31, 2018, Janssen appealed to the Court of Appeals for the Federal Circuit the district court's judgment that the '438 patent was invalid as obvious. No. 15-cv-5909, ECF

[5] https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/208446Orig1s000ltr.pdf (last accessed April 21, 2023).

No. 573.

MPI launched its product on November 21, 2018.

2. Proceedings at the Patent Trial and Appeal Board

The district court litigation was not the only proceeding that found the '438 patent invalid as obvious. On June 30, 2016, MPI filed a petition for *inter partes* review ("IPR") of the '438 patent, seeking an order from the U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") that the '438 patent's claims were unpatentable as obvious. Pet., *Mylan Pharms. Inc. v. Janssen Oncology, Inc.*, IPR2016-01332, Paper 1 (PTAB June 30, 2016). The MPI-initiated IPR review was one of five IPRs filed on the same or similar grounds to challenge validity of the '438 patent. *See also* IPR2016-00286 (by Amerigen), IPR2016-01317 (by Argentum), IPR2016-01582 (by Wockhardt), and IPR2017-00853 (by Amneal).

On January 17, 2018, the PTAB found that the claims of the '438 patent were unpatentable, i.e., invalid, as obvious over the prior art. *See, e.g.*, *Mylan*, IPR2016-01332, Paper 84.[6] Janssen appealed the PTAB's final written decision to the Federal Circuit.

3. Consolidated Appeal Proceedings at the Federal Circuit

The Federal Circuit held a combined hearing on Janssen's appeals of the district court and PTAB's rulings. *BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1065-66 (Fed. Cir. 2019). Focusing on the Wockhardt-initiated *inter partes* review proceeding (IPR2016-01582), the Federal Circuit affirmed the PTAB's finding that the claims of the '438 patent were unpatentable (i.e., invalid) as obvious. *Id.* at 1073-77. The Federal Circuit dismissed as moot the appeals of all other actions, including the district court litigation and the MPI-initiated *inter partes* review. *Id.* at 1066 n.2, 1077.

[6] The PTAB reached the same decision in each of the *inter partes* reviews related to the '438 patent where it issued a final written decision, finding it invalid as obvious in each instance.

D. The *Qui Tam* Litigation

MPI is not a party to the present *qui tam* case. This action was originally brought against Janssen in the Northern District of California in 2017, and the action was transferred to this District in 2019. *See United States of America v. Janssen Biotech, Inc.*, No. 4:17-cv-07250 (N.D. Cal. Apr. 29, 2019), ECF 51 (order granting motion to transfer venue). On September 24, 2018, the Government declined to intervene. *Id.*, ECF 6 (Government's Notice of Election to Decline Intervention and Order regarding procedure).

In May 2021, Relator contacted MPI through counsel, seeking discovery of MPI's documents produced in the ANDA case. These documents were and still are in Janssen's possession, after Janssen neglected to destroy them at the conclusion of that case, as required by the protective order in that case. *See* ECF 218 at 5-6 (explaining the same); No. 15-cv-5909, ECF 634 (same). After extended negotiations with both Relator and Janssen, MPI declined to allow Janssen to produce those documents in discovery. In May 2022, Relator filed two motions related to this dispute: 1) a motion to compel Janssen to produce MPI's documents from the ANDA case that remained in Janssen's possession, and 2) a motion to amend the *qui tam* discovery confidentiality order to allow Relator to review the produced documents. This Court denied both motions. *United States ex rel. Silbersher v. Janssen Biotech, Inc.*, 2022 WL 17250563, at *5 (D.N.J. Nov. 28, 2022). Regarding Relator's motion to compel discovery, in particular, the Court acknowledged that "any qui tam case may arguably involve issues that are important to the public," but also found Relator's supporting reasoning, based on alleged "evidence that [Janssen's] misconduct delayed Mylan's market entry," "to be borderline speculative." *Id.* at *4.

Janssen served a subpoena on MPI on March 6, 2023.[7] Janssen's document requests are both duplicative and cumulative of the document productions that this Court already refused to compel, and significantly broader and more invasive. The requests include, for example:

- All documents and communications relating to planning or analysis for developing or marketing your abiraterone acetate product or a product containing abiraterone acetate;
- All documents relating to Mylan's establishment of a wholesale acquisition cost and/or average wholesale price for NDC No. 00378-6920-78, including any press releases, email announcements, or other communications with any drug price listing service or any other entity;
- All documents sufficient to identify any other entities involved in the manufacturing, labeling, relabeling, assembly, preparation, or inventorying of abiraterone acetate or Mylan's product containing abiraterone acetate, including but not limited to any contracts with other entities involved in the manufacturing of the active pharmaceutical ingredient or any other part of your abiraterone acetate product;
- All documents or communications relating to any agreements with any wholesalers, retail pharmacies, specialty pharmacies, or any other potential purchasers or distributors involved in the distribution of Mylan's generic abiraterone acetate product;
- All documents and communications relating to whether Mylan would be able to supply sufficient abiraterone acetate product to meet expected demand upon FDA approval; and
- All documents relating to Mylan's business plans and strategy, including timing, to file an ANDA for generic abiraterone acetate and any changes to that strategy and/or timing.

Ex. K (Subpoena from Janssen to nonparty Mylan Pharmaceuticals Inc.) at 7-8. For at least the reasons below, this Court should grant MPI's motion to quash Janssen's subpoena.

III. LEGAL STANDARD

"The Federal Rules of Civil Procedure contain a clear set of instructions regarding how subpoenas for documents, and also disputes related to such subpoenas, are to be handled." *In re Disposable Contact Lens Antitrust Litig.*, 306 F. Supp. 3d 372, 375 (D.D.C. 2017). As a threshold

[7] In exchange for accepting service of the subpoena, Janssen consented to MPI serving its response to the subpoenas no later than April 21, 2023. *See* Ex. J (email correspondence between Reid and White) at 1 (agreeing to date).

matter, a nonparty subpoena must comply with the requirements of Federal Rule of Civil Procedure 45. If the subpoena "requires a person to comply beyond the geographical limits specified in Rule 45(c)" (within 100 miles of where the person resides, is employed, or regularly transacts business in person) then the court "*must* quash or modify the subpoena" Fed. R. Civ. P. 45(c)(3)(A) (emphasis added).

If the geographic requirements are met, the Court must ensure a subpoena "served in conjunction with discovery must fall within the scope of proper discovery under Fed. R. Civ. P. 26(b)(1)." *Schmulovich v. 1161 Rt. 9 LLC,* 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007). The court "must limit the . . . extent of discovery" where it is duplicative; where it can be obtained from another source that is "more convenient, less burdensome, or less expensive"; where the party seeking discovery has had ample opportunity to obtain the discovery; or where the burden or expense outweighs any perceived benefit of the discovery. Fed. R. Civ. P. 26(b)(2)(C)(i)–(iii). The right to discovery is not unlimited and does have "ultimate and necessary boundaries." *Hickman v. Taylor*, 329 U.S. 495, 507 (1947).

It is well established that a nonparty to an action is "afford[ed] greater protection . . . in discovery, and nonparty subpoenas must meet a higher standard of relevance than subpoenas directed toward parties." *Conforti v. St. Joseph's Healthcare Sys., Inc.*, 2019 WL 3847994, at *2 (D.N.J. Aug. 15, 2019); *Walgreens Specialty Pharm., LLC v. Atrium Admin. Servs., Inc.*, 2020 WL 6042280, at *3 (D.N.J. Oct. 13, 2020) (internal quotation marks omitted); *see also Stamy v. Packer*, 138 F.R.D. 412, 419 (D.N.J. 1990) (noting "standards for nonparty discovery require a stronger showing of relevance than for simple party discovery").

Under Rule 45, "courts have significant discretion to quash or modify a subpoena where the discovery sought is irrelevant, or compliance with the subpoena would be unreasonable and

oppressive." *Walgreens*, 2020 WL 6042280, at *3 (internal citations and quotation marks omitted). To determine whether a subpoena is "unreasonable or oppressive," the moving party need only show that, on balance, the following factors weigh in favor of quashing the subpoena: "(1) the party's need for the production; (2) the nature and importance of the litigation; (3) the relevance of the material; (4) the breadth of the request for production; (5) the time period covered by the request; (6) the particularity with which the documents are described; and (7) the burden imposed on the subpoenaed party." *In re Lazaridis*, 865 F. Supp. 2d 521, 524 (D.N.J. 2011); *Strike 3 Holdings, LLC v. Doe*, 2019 WL 4745360, at *5 (D.N.J. Sept. 30, 2019).

As described below, the subpoena should be quashed because it seeks information irrelevant to issues in the present case, is overbroad, and imposes a substantial and undue burden on MPI. *See* Fed. R. Civ. P. 45(c)(3)(A)(iv).

IV. ARGUMENT

A. Janssen's Subpoena is Procedurally Invalid.

The Court should quash Janssen's subpoena because they require MPI to comply beyond 100 miles, the geographical limit specified in Rule 45. Fed. R. Civ. P. 45(c)(3)(A); *see also W. Coast Life Ins. Co. v. Life Brokerage Partners, LLC*, 2010 WL 181088, at *2 (D. Del. Jan. 19, 2010) (quashing a third-party subpoena because nonparty "demonstrated that its employees work more than 100 miles from Wilmington" and so "the court will quash the subpoena in this regard."). Rule 45 requires the production of documents to occur "at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person." Fed. R. Civ. P. 45 (c)(2). Even though the rule is clear—in fact, Janssen attached the rule to the issued subpoena—Janssen failed to meet this basic requirement. Rather, Janssen specified that compliance should occur in Newark, NJ. *See* Ex. K (Subpoena to nonparty MPI) at 1. But MPI does not reside or regularly transact business in person within 100 miles of Newark, NJ. Rather, MPI resides in Morgantown,

West Virginia. *See, e.g.*, *In Re: Ozempic (Semaglutide) Patent Litig.*, No. 22-md-3038, ECF 116 (Apr. 12, 2023) ¶ 5 (MPI is "a corporation organized and existing under the laws of the State of West Virginia," with "a principal place of business at 3711 Collins Ferry Road, Morgantown, WV 26505"). Thus, Janssen's subpoena should be quashed on at least this basis.

B. The *Lazaridis* Factors Favor Quashing the Subpoena.

All seven *Lazaridis* factors on balance weigh in favor of quashing the Janssen subpoena as unreasonable and oppressive.

1. Factor One: Janssen Does Not Need the Requested Documents.

Janssen does not need this production. When measuring a party's need for evidence, courts look to a variety of factors, including the need to prepare an adequate defense or establish a claim, the availability of alternative evidence, the need to cross-examine expert witnesses, and the need for the underlying data. *See Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556, 561–63 (7th Cir. 1984). Considering these factors, Janssen cannot demonstrate a need for the broad information it seeks from MPI with the subpoena.

MPI launched its abiraterone product at the earliest possible moment. There is no credible theory set forth in the Relator's Complaint that MPI could have launched any earlier than it did. Any suggestion to the contrary is inconsistent with the governing statutes and regulations, including the Hatch-Waxman Act and GDUFA, and the FDA's practice of actively approving other abiraterone acetate products for the same market. When MPI launched, it launched into a competitive marketplace with competition involving multiple products from Janssen and other branded and generic competitors. The discovery sought from MPI is burdensome, speculative, duplicative of public information, and irrelevant in view of these incontrovertible and public facts.

MPI, through counsel, has repeatedly represented to Relator and Janssen, and MPI made clear in its opposition to Relator's earlier motion to compel, that MPI does not have any discrete

or unique documents that would indicate its readiness to enter the abiraterone acetate market but for the litigation on the '438 patent. ECF 216 at 8-10 (explaining how MPI could not have launched its generic abiraterone ANDA product any earlier than October 31, 2018). The reason for this is simply because such an analysis is not undertaken by generic companies in the usual course of developing a generic drug product, and this was the case here for MPI's development of its abiraterone ANDA product. Instead, MPI was preparing to enter the market upon the FDA's approval, which it expected around the time the 30-month stay of approval expired. This can be understood from documents that are *already* available to Janssen, including the FDA's publicly available approval letter,[8] which includes the ANDA filing and approval dates, and information from publicly available sources. *See* ECF 216 at 8-10; *see also SAJ Distributors, Inc.*, 2008 WL 2668953, at *2 ("To require a non-party to search for additional documents that it has certified do not exist is an undue burden that would result in the waste of counsels' resources, and, more importantly, a waste of the client's funds.").

2. Factor Two: The Nature and Importance of the Litigation Favors Quashing.

The nature of the suit also favors quashing. As mentioned above, the Government declined to intervene in this matter and, as this Court has found, this case "does not raise issues concerning public health and safety. Silbersher has not alleged that anyone covered by government health programs who needed a prescription for Zytiga following a prostate-cancer diagnosis was denied coverage due to its expense or the lack of a generic alternative." *United States ex rel. Silbersher*, 2022 WL 17250563, at *3. In fact, it would be hard to imagine such a circumstance existing, given

[8] The FDA's approval letter for MPI's ANDA can be found on the publicly accessible Drugs@FDA website. Ex. A; *see also* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=208446

the number of competitors in the market for abiraterone acetate products, now and at the time of MPI's launch. Indeed, by the time MPI launched its product after the FDA's approval, the market was already being served by multiple products from Janssen and other generic and branded suppliers, meaning both cost and availability were not an issue.

Further, to the extent the subpoena seeks financial information concerning the sales of generic or other alternative abiraterone products to the Federal government, such discovery is best sought from the Federal government, on whose behalf this case is being prosecuted. Any differences between what the Federal government paid before generic entry and following generic entry are readily obtainable from the Federal government agencies on whose behalf this case is prosecuted.

3. Factor Three: The Requested Material is Tangential and Not Relevant.

The subpoena should be quashed because it does not seek relevant material. Discovery should be denied "where, in the court's judgment, the inquiry lies in a speculative area." *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1326 (Fed. Cir. 1990). A requestor's "mere suspicion is not enough to warrant such a broad inquiry. Subpoenaed information is not relevant to subject matter involved in the pending action if the inquiry is based on the party's mere suspicion or speculation." *Hashem v. Hunterdon Cty.*, 2017 WL 2215122, at *3 (D.N.J. May 18, 2017) (internal quotation marks and citations omitted). In addition, "the standards for non-party discovery require a stronger showing of relevance than for simple party discovery." *Stamy v. Packer*, 138 F.R.D. 412, 419 (D.N.J. 1990).

Here, the Court has already noted that Relator's theory of the case is "borderline speculative." *Id.* at *4. Documents from MPI cannot be relevant to whether Janssen committed fraud against the United States. Those documents are in the possession of Janssen and the United

States. Rather, at most, the documents sought from MPI would relate tangentially to Relator's damages claims.

Further, as noted in MPI's opposition to Relator's earlier motion to compel document production, MPI's documents cannot be relevant to the claims in this case. As the Court recognizes, Relator's theory of the case is "that by extending its patent-based monopoly, Janssen fraudulently inflated the cost of abiraterone acetate tablets, thereby causing Medicare and other federal and state government health programs to pay inflated prices to Janssen to cover Zytiga's full cost at taxpayer expense for those insured by the government health programs." *United States ex rel. Silbersher*, 2022 WL 17250563, at *2. However, MPI's entry into the market, and any effect that might have had on the price and supply of abiraterone in the marketplace, was dictated by both existing regulatory exclusivity and by the timing of the FDA's approval process. The first of these, the NCE-1 regulatory exclusivity, was determined by the date of initial approval of Janssen's Zytiga product and set the date on which MPI could submit its ANDA. The second of these, the timing of the FDA's review and approval process for MPI's ANDA, was dictated by GDUFA II and the FDA's adherence to those statutory guidelines, which set the date on which the FDA could deem MPI's ANDA finally approvable. MPI's market participation was therefore not determined by any improper patent monopoly that Janssen may have attempted to create. ECF 216 at 8-10 (MPI could not have launched its generic abiraterone ANDA product before October 31, 2018).

Finally, the documents requested by Janssen, which are focused on MPI's pre-launch activities, cannot inform the question of whether *Janssen* inflated its prices, which the government was then forced to pay, *before* the *FDA approved MPI to launch its ANDA product*. Those pricing decisions, and the prices the government then paid, were necessarily determined by the market as it existed before MPI's approval and launch, which contained multiple abiraterone products from

Janssen and other suppliers. Information about the availability of MPI's ANDA product after its launch and as it entered this active marketplace is a matter of public record.[9] Thus, nothing requested in the Janssen subpoena is relevant to the claims and defenses in this litigation, and this lack of relevance is a sufficient basis to grant the motion to quash. *ExteNet Sys., Inc. v. Twp. of North Bergen*, 2021 WL 5782977, at *3 (D.N.J. Dec. 7, 2021).

A nonparty should not be burdened by extensive document discovery based solely on a "speculative" case theory, especially when the nonparty's information is not relevant to that theory.

4. Factors Four, Five, and Six: The Requests are Broad with An Expansive Time Period and Lack Particularity.

Janssen's subpoena requests either very broad categories of information without any time periods specified to limit the requests, or overbroad categories of documents. For example, the requests include:

- All documents and communications relating to planning or analysis for developing or marketing your abiraterone acetate product or a product containing abiraterone acetate;
- All documents sufficient to identify any other entities involved in the manufacturing, labeling, relabeling, assembly, preparation, or inventorying of abiraterone acetate or Mylan's product containing abiraterone acetate, including but not limited to any contracts with other entities involved in the manufacturing of the active pharmaceutical ingredient or any other part of your abiraterone acetate product;
- All documents or communications relating to any agreements with any wholesalers, retail pharmacies, specialty pharmacies, or any other potential purchasers or distributors involved in the distribution of Mylan's generic abiraterone acetate product;
- All documents and communications relating to whether Mylan would be able to supply sufficient abiraterone acetate product to meet expected demand upon FDA approval; and
- All documents relating to Mylan's business plans and strategy, including timing, to file an ANDA for generic abiraterone acetate and any changes to that strategy and/or timing.

[9] For example, IQVIA is a company that gathers detailed data on the sales of pharmaceuticals, providing detailed product-level reports, including various wholesale and retail costs sought by Janssen's subpoena. These reports are available to any IQVIA customer.

Ex. K (Subpoena from Janssen to nonparty Mylan Pharmaceuticals Inc.) at 7-8.

Responding to the breadth of these requests would impose a significant burden on MPI. First, MPI would be required to engage the relevant custodians and search other shared sources, along with assistance from in-house attorneys and IT professionals, to collect this information, which potentially dates back more than *ten years* to January 1, 2013. *Id.* at 6 (the "default date range for the Requests is January 1, 2013 through May 31, 2020 unless otherwise specified"). Second, the custodians of potentially relevant documents would include both current and former employees, and span multiple teams within each company, including marketing, finance, sales, manufacturing, and supply chain teams. Third, the collection would likely span multiple geographies, both domestic and overseas. Fourth, once the proper custodians and sources are identified, all collected documents would need to be reviewed for privilege, responsiveness, and confidentiality, at considerable expense. It would be unreasonable and oppressive to require a disinterested third-party to conduct this kind of collection, review, and production. *See N.C. Right to Life, Inc. v. Leake*, 231 F.R.D. 49, 52 (D.D.C. 2005) (finding subpoena constituted undue burden on nonparty large organization that certified compliance would require "the time of at least four to six staff members for a month, and could require more time on the part of [its] inside and outside counsel").

5. Factor Seven: MPI is Unduly Burdened Because of the Highly Confidential, Sensitive Nature of the Material Requested.

In addition to the overbroad and expansive requests, Janssen's subpoena seeks highly confidential, sensitive financial and business information and know-how from MPI. Production of such materials would cause immeasurable harm to MPI because it would produce these competitive documents to Janssen, its *brand competitor* against whom MPI is actively competing in the market.

Under Rule 45, a court may quash or modify a subpoena if it requires "disclosing a trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 45(d)(3)(B)(i). For example, in *PPL Energy Plus, LLC v. Solomon*, plaintiffs subpoenaed non-party PJM, seeking information and documents concerning the wholesale electricity markets operated by PJM that would potentially disclose the confidential information. 2013 WL 12123337, at *1 (D.N.J. Jan. 18, 2013). The Court granted in part the nonparty's motion to quash because the subpoena "would effectively require the Participants to disclose confidential and proprietary business information to their competitors." The court explained further that this "fact alone presents significant hardships—especially in light of the Participants' non-party status in this action." *Id.*; *see also Friedman v. Dollar Thrifty Auto. Grp., Inc.*, 2014 WL 12767360, at *2 (D.N.J. Dec. 18, 2014) (quashing non-party subpoena where "the information sought is confidential business information, the disclosure of which would be harmful" to the non-party.).

Similarly, here, Janssen's subpoena seeks highly confidential business information from MPI that will be produced directly to its competitor, Janssen. For example, Janssen's requests seek the following sensitive information: "planning or analysis for developing or marketing your abiraterone acetate product or a product containing abiraterone acetate," "the submission or approval of the label or other labeling of Mylan's ANDA No. A208446, including any [structured product labeling] submissions," "Mylan's establishment of a wholesale acquisition cost and/or average wholesale price for NDC No. 00378-6920-78," the identity of " any other entities involved in the manufacturing, labeling, relabeling, assembly, preparation, or inventorying of abiraterone acetate or Mylan's product containing abiraterone acetate, including but not limited to any contracts with other entities involved," "any agreements with any wholesalers, retail pharmacies, specialty pharmacies, or any other potential purchasers or distributors involved in the distribution

of Mylan's generic abiraterone acetate product," and "whether Mylan would be able to supply sufficient abiraterone acetate product to meet expected demand." Ex. K (Subpoena from Janssen to nonparty Mylan Pharmaceuticals Inc.) at 7-8. While there is a protective order in place that would limit access to this information, the possibility of inadvertent disclosure to unauthorized parties or individuals during the litigation, disclosure at trial or otherwise, or Janssen's failure to deal appropriately with those documents, would cause substantial harm to MPI, and outweighs Janssen's need for the information. MPI would also be forced to attempt to protect its highly confidential information from public disclosure if either party to this litigation sought to file it as part of a paper (MPI would bear the burden, each time, of convincing the Court to keep MPI's information under seal). *See* ECF 175 at 14 (describing burdens and procedures related to sealing). But aside from its forced role in trying to avoid unwanted public disclosures, MPI would have little or no control over disclosure of its highly confidential information and how it is used in the case. The highly sensitive data that Janssen seeks regarding MPI's business practices, product planning, financial projections, market shares, costs, and profits is therefore unduly burdensome to ask nonparty MPI to produce in this action. *See SAJ Distribs., Inc.*, 2008 WL 2668953, at *3 (granting motion to quash "[i]n order to prevent non-party [generic] from the undue burden imposed by having to disclose highly sensitive sales information and from having to produce additional data beyond the scope of the original subpoena.").

V. CONCLUSION

For the foregoing reasons, MPI respectfully requests that the Court grant its motion to quash Janssen's subpoena.[10]

[10] To the extent the Court is not inclined to quash the Janssen subpoena, MPI respectfully requests that the scope of the subpoena be materially narrowed to lessen the burden required for MPI to respond.

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